

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS,
SHERMAN DIVISION

BIOTE MEDICAL, LLC,

Plaintiff,

v.

Case No. _____

**KENT JACOBSEN, JENI GUINN,
DANIEL D. DENEUI, TERRI J.
DENEUI, MICHAEL S. COLE,
JEFF DENEUI, DUSTIN C. DENEUI,
JOHN THOMAS, MD, GUNTHER,
MUELLER, DAN MIKALS,
LISA MIKALS, MARK BURNS,
WENDY SANDOVAL, NICOLE
TURCOTTE, DOMINIC VERRILLI,
KIMBERLY MEEGAN, ANDREA
C. JONES, JUSTIN GRAVES,
ROBERT ALAN HARRIS, MARTIN
GROVES, NEAL ROUZIER, MD,
MICHAEL SHEFFIELD, MD,
FORGET ABOUT IT, INC.,
SUTHERLAND SOLUTIONS, LLC,
EVEXIAS HEALTH SOLUTIONS, LLC,
EVEXIPEL, a Division of Evexias
Health Solutions, LLC, EVEXIAS
HOLDING CO, LLC, EVEXIAS HRT,
LLC f/k/a Hormonal Health and
Wellness Centers, LLC,
EVEXIAS MEDICAL CENTERS, PLLC
f/k/a Terri Suresh ACNP, PLLC a/k/a
Hormonal Health Wellness & Skin
Center a/k/a Hormonal Health
Wellness and Aesthetics Center
a/k/a Hormonal Health & Wellness,
EVEXIAS MANAGEMENT, LLC,
EVEVIAS METRITA-COLUMBIA, LLC,
EVEXIAS-ANTHEM COLUMBIA, LLC,
EVEXIAS-ANTHEM ALASKA, LLC,
NORTH AMERICAN CUSTOM
LABORATORIES, LLC a/k/a
FARMAKEIO, FARMAKEIO
NUTRACEUTICALS, LLC,
FARMAKEIO OUTSOURCING, LLC,
and NILUS, LLC,**

Defendants.

**BIOTE MEDICAL, LLC'S ORIGINAL COMPLAINT
AND APPLICATION FOR INJUNCTIVE RELIEF**

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

COMES NOW, BioTE Medical, LLC (“BioTE” or “Plaintiff”) and files this, its Original Complaint and Application for Injunctive Relief complaining of and against KENT JACOBSON, JENI GUINN, DANIEL D. DENEUI, TERRI J. DENEUI, MICHAEL S. COLE, JEFF DENEUI, DUSTIN C. DENEUI, JOHN THOMAS, MD, GUNTHER MUELLER, DAN MIKALS, LISA MIKALS, MARK BURNS, JEFF HILL, WENDY SANDOVAL, NICOLE TURCOTTE, DOMINIC VERRILLI, KIMBERLY MEEGAN, ANDREA C. JONES, JUSTIN GRAVES, ROBERT ALAN HARRIS, MARTIN GROVES, NEAL ROUZIER, MD, MICHAEL SHEFFIELD, MD, FORGET ABOUT IT, INC., SUTHERLAND SOLUTIONS, LLC, EVEXIAS HEALTH SOLUTIONS, LLC, EVEXIPEL, a Division of Evexias Health Solutions, LLC, EVEXIAS HOLDING CO, LLC, EVEXIAS HRT, LLC f/k/a Hormonal Health and Wellness Centers, LLC, EVEXIAS MEDICAL CENTERS, PLLC f/k/a Terri Suresh ACNP, PLLC a/k/a Hormonal Health Wellness & Skin Center a/k/a Hormonal Health Wellness and Aesthetics Center a/k/a Hormonal Health & Wellness, EVEXIAS MANAGEMENT, LLC, EVEVIAS METRITA-COLUMBIA, LLC, EVEXIAS-ANTHEM COLUMBIA, LLC, EVEXIAS-ANTHEM ALASKA, LLC, NORTH AMERICAN CUSTOM LABORATORIES, LLC a/k/a FARMAKEIO, FARMAKEIO NUTRACEUTICALS, LLC, FARMAKEIO OUTSOURCING, LLC, and NILUS, LLC (all collectively the “Defendants”); and, in support thereof, would respectfully show the Court as follows:

I.
PARTIES

1. BioTE Medical, LLC is a limited liability company organized under the laws of the State of Texas, and is the successor corporation of SottoPelle Texas, LLC, with its principal place of business located at 1875 W. Walnut Hill Lane, Suite 100, Irving, Dallas County, Texas 75038.

2. Kent Jacobsen, also known as James K. Jacobsen (“**Jacobsen**”), is an individual residing in the State of Texas and may be served with process at his residence located at 4029 Boren Court, Plano, Texas 75023, or wherever else he may be found.

3. Jeni Guinn, also known as Jennifer Guinn (“**Guinn**”), is an individual residing in the State of Texas and may be served with process at her usual place of business located at 700 North Carroll Avenue, Suite 110, Southlake, Texas 76092 or her residence located at 9705 Presthope Drive, Frisco, Texas 75035, or wherever else she may be found.

4. Daniel D. DeNeui (“**Dan DeNeui**”) is an individual residing in the State of Texas and may be served with process at his usual place of business located at 620 North Kimball, Southlake, Tarrant County, Texas 76092, or his residence located at 4505 Bowman Drive, Colleyville, Tarrant County, Texas 76034, or wherever else he may be found.

5. Terri J. DeNeui (“**Terri DeNeui**”) is an individual residing in the State of Texas and may be served with process at her usual place of business located at 620 North Kimball, Southlake, Tarrant County, Texas 76092, or her residence located at 4505 Bowman Drive, Colleyville, Tarrant County, Texas 76034, or wherever else she may be found.

6. Michael S. Cole (“**Michael Cole**”) is an individual residing in the State of Texas and may be served with citation at his usual place of business located at 700 N. Carroll, Southlake,

Tarrant County, Texas 76092, or his residence located at 1025 Southview Trail, Southlake, Tarrant County, Texas 76092, or wherever else he may be found.

7. Jeff DeNeui, also known as Jonathan DeNeui (“**Jeff DeNeui**”), is an individual residing in the State of Colorado and may be served with process at his residence located at 6550 Ashburn Lane, Highlands Ranch, Colorado 80130, or wherever else he may be found.

8. Dustin C. DeNeui (“**Dustin DeNeui**”) is an individual residing in the State of Texas, but doing business in the State of Texas, and may be served with process at his usual place of business located at 620 North Kimball, Southlake, Tarrant County, Texas 76092 or his residence located at 307 West Ash Lane, Euless, Texas 76039, or wherever else he may be found

9. John Thomas (“**Thomas**”) is an individual residing in the State of Texas and may be served with process at his usual place of business located at 1120 West Loop 289, Suite 230, Lubbock, Texas 79416, or wherever else he may be found.

10. Gunther Mueller (“**Mueller**”) is an individual residing in the State of Colorado, but doing business in the State of Texas, and may be served with process at his residence located at 7 Willowleaf Drive, Littleton, Colorado 80127, or wherever else he may be found.

11. Dan Mikals (“**Dan Mikals**”) is an individual residing in the State of Texas and may be served with process at his usual place of business located at 700 North Carroll Avenue, Suite 110, Southlake, Texas 76092 or residence located at 1403 Woodridge Circle, Euless, Texas 76040, or wherever else he may be found.

12. Lisa Mikals (“**Lisa Mikals**”) is an individual residing in the State of Texas and may be served with process at her usual place of business located at 700 North Carroll Avenue, Suite 110, Southlake, Texas 76092 or residence located at 1403 Woodridge Circle, Euless, Texas 76040, or wherever else she may be found.

13. Mark P. Burns (“**Burns**”) is an individual residing in the State of Florida, but doing business in the State of Texas, and may be served with process at his residence located at 4808 Tuscan Loon Drive, Tampa, Hillsborough County, Florida 33619, or wherever else he may be found.

14. Jeff Hill (“**Hill**”) is an individual residing in the State of Florida, but doing business in the State of Texas and may be served with process at his residence located at 1570 Arden Street, Longwood, Florida 32750, or wherever else he may be found.

15. Wendy Sandoval, also known as Wendy Singer (“**Sandoval**”), is an individual residing in the State of New Mexico, but doing business in the State of Texas and may be served with process at her residence located at 1500 Luz De Sol Drive, Rio Rancho, New Mexico 87124, or wherever else she may be found.

16. Nicole Turcotte (“**Turcotte**”) is an individual residing in the State of Arizona, but doing business in the State of Texas, and may be served with process at her residence located at 42424 N. Gavilan Peak Parkway, Anthem, Maricopa County, Arizona 85086, or wherever else she may be found.

17. Dominic Verrilli (“**Verrilli**”) is an individual residing in the State of Ohio, but doing business in the State of Texas, and may be served with process at his residence located at 5372 Thistledown Drive, Columbus, Ohio 43221, or wherever else he may be found.

18. Kimberly Meegan (“**Meegan**”) is an individual residing in the State of Texas and may be served with process at her residence located at 18902 North FM 1584, Big Spring, Texas 79720 or 7436 Timberhill Road, North Richland Hills, Texas 76182, or wherever else she may be found.

19. Andrea C. Jones (“**Jones**”) is an individual residing in the State of Texas and may be served with process at her usual place of business located at 96 Monticello Drive, Mansfield, Tarrant County, Texas 76063, or wherever else she may be found.

20. Justin Graves (“**Graves**”) is an individual residing in the State of Texas and may be served with process at his residence located at 1664 Rabbit Ridge Road, Rockwall, Texas 75032, or wherever else he may be found.

21. Robert Alan Harris (“**Harris**”) is an individual residing in the State of Texas and may be served with process at his residence located at 2000 Serenity Avenue, Wylie, Texas 75098, or wherever else he may be found.

22. Martin Groves (“**Groves**”) is an individual residing in the State of Texas and may be served with process at his usual place of business located at 700 North Carroll Avenue, Suite 110, Southlake, Texas 76092 or residence located at 5711 Teal Court, Sachse, Texas 75048, or wherever else he may be found.

23. Neal Rouzier, M.D. (“**Rouzier**”) is an individual residing in the State of California, but doing business in the State of Texas, and may be served with process at his residence located at 1353 Verdugo Road, Palm Springs, California 92262, or wherever else he may be found.

24. Michael Sheffield, M.D. (“**Sheffield**”) is an individual residing in the State of Texas and may be served with process at his usual place of business located at 1441 North Beckley Avenue, Dallas, Texas 75203 or his residence located at 4005 Sahara Court, Carrollton, Texas 75010, or wherever else he may be found.

25. Forget About It, Inc. (“**FAI**”) is a corporation organized under the laws of the State of Colorado with its principal place of business located at 7 Willowleaf Drive, Littleton, Jefferson

County, Colorado 80127, but doing business in the State of Texas, and may be served with process by serving its registered agent, Gunther Mueller, at 7 Willowleaf Drive, Littleton, Colorado 80127.

26. Sutherland Solutions, LLC (“**Sutherland**”) is a limited liability company organized under the laws of the State of Texas, with its principal place of business located at 1025 Southview Trail, Southlake, Tarrant County, Texas 76092. Sutherland may be served with process by serving its registered agent, Michael S. Cole, at 1025 Southview Trail, Southlake, Tarrant County, Texas 76092, or wherever else he may be found.

27. Evexias Health Solutions, LLC (“**Evexias Health Solutions**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 4505 Bowman Drive, Colleyville, Tarrant County, Texas 76034. Evexias Health Solutions may be served with process by serving its registered agent, Terri DeNeui, at 4505 Bowman Drive, Colleyville, Tarrant County, Texas 76034, or wherever else she may be found.

28. EvexiPEL, is a Division of Evexias Health Solutions (“**EvexiPEL**”), doing business in the State of Texas, and may be served with process by serving its registered agent, Terri DeNeui, at 4505 Bowman Drive, Colleyville, Tarrant County, Texas 76034, or wherever else she may be found.

29. Evexias Holding Co, LLC (“**Evexias Holding Co.**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 4505 Bowman Drive, Colleyville, Texas 76034. Evexias Holding Co. may be served with process by serving its registered agent, United States Corporation Agents, Inc., at 9900 Spectrum Drive, Austin, Texas 78717.

30. Evexias HRT, LLC f/k/a Hormonal Health and Wellness Centers, LLC (“**Evexias HRT**”) is a limited liability company organized under the laws of the State of Texas with its

principal place of business located at 620 N. Kimball Avenue, Ste. 100, Southlake, Tarrant County, Texas 76092. Evexias HRT may be served with process by serving its registered agent, Terri J. DeNeui, at 521 W. Southlake Blvd., #100, Southlake, Tarrant County, Texas 76092, or wherever else she may be found.

31. Evexias Medical Centers, PLLC f/k/a Terri Suresh ACNP, PLLS a/k/a Hormonal Health Wellness & Skin Center a/k/a Hormonal Health Wellness and Aesthetics Center a/k/a Hormonal Health & Wellness (“**Evexias Medical Centers**”) is a professional limited liability company organized under the laws of the State of Texas with its principal place of business located at 620 N. Kimball Avenue, Ste. 100, Southlake, Tarrant County, Texas 76092. Evexias Medical Centers may be served with process by serving its registered agent, Terri J. DeNeui, at 521 W. Southlake Blvd., #100, Southlake, Tarrant County, Texas 76092, or wherever else she may be found.

32. Evexias Management, LLC (“**Evexias Management**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 1025 Southlake Trail, Southlake, Texas 76092. Evexias Management may be served with process by serving its registered agent, Michael S. Cole, at 1025 Southview Trial, Southlake, Texas 76092, or wherever else he may be found.

33. Evexias Metrita-Columbia, LLC (“**Evexias Metrita Columbia**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 206 E. 9th Street, Suite 1300, Austin, Texas 78701. Evexias Metrita Columbia may be served with process by serving its registered agent, Capitol Corporate Services, Inc., at 206 E. 9th Street, Suite 1300, Austin, Texas 78701.

34. Evexias-Anthem Columbia, LLC (“**Evexias Anthem Columbia**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 913 S. Main Street, Unit 212, Grapevine, Texas 76051. Evexias Anthem Columbia may be served with process by serving its registered agent, Steve House, at 913 S. Main Street, Unit 212, Grapevine, Texas 76051, or wherever else he may be found.

35. Evexias-Anthem Alaksa, LLC (“**Evexias Anthem Alaska**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 206 E. 9th Street, Suite 1300, Austin, Texas 78701. Evexias Anthem Alaska may be served with process by serving its registered agent, Capitol Corporate Services, Inc., at 206 E. 9th Street, Suite 1300, Austin, Texas 78701.

36. North American Custom Laboratories, LLC a/k/a Farmakeio (“**Farmakeio**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 1736 N. Greenville Avenue, Richardson, Dallas County, Texas 75081. NACL may be served with process by serving its registered agent, Capitol Corporate Services, Inc., at 206 E. 9th Street, Suite 1300, Austin, Texas 78701.

37. Farmakeio Nutraceuticals, LLC (“**Farmakeio Nutraceuticals**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 700 N. Carroll Avenue, Suite 110, Southlake, Texas 76092. Farmakeio Nutraceuticals may be served with process by serving its registered agent, Capitol Corporate Services, Inc., at 206 E. 9th Street, Suite 1300, Austin, Texas 78701.

38. Farmakeio Outsourcing, LLC (“**Farmakeio Outsourcing**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 4505 Bowman Drive, Colleyville, Texas 76034. Farmakeio Outsourcing may be served with

process by serving its registered agent, Evexias Holding Co, LLC, by serving its registered agent, United States Corporation Agents, Inc., at 9900 Spectrum Drive, Austin, Texas 78717.

39. Nilus, LLC (“**Nilus**”) is a limited liability company organized under the laws of the State of Texas with its principal place of business located at 307 W. Ash Lane, Euless, Tarrant County, Texas 76039. Nilus may be served with citation by serving its registered agent, Dustin C. DeNeui, at 2801 Brazos Blvd., #4308, Euless, Tarrant County, Texas 76039, or wherever else he may be found.

II. **JURISDICTION & VENUE**

40. Jurisdiction is proper in this Court on the basis of federal question in accordance with 28 U.S.C. § 1331.

41. Venue is proper in the Eastern District of Texas, Sherman Division, in accordance with 28 U.S.C. § 1391 because all or a substantial part of the acts or omissions giving rise to the claim occurred in the Eastern District of Texas.

III. **SUMMARY OF THE CASE**

42. Defendants are engaged in a pernicious, illegal, and extensive enterprise to manufacture, market, sell and distribute illegal drugs throughout the United States. While undeniably less violent than the drug cartels infiltrating the United States, Defendants’ illegal distribution of their products through ostensibly legitimate and otherwise trusted channels poses no less a public health risk; for the express purpose of personal gain and profit. Indeed, by openly and brazenly using licensed medical doctors and practitioners as their mules to sell their drugs to unsuspecting and trusting patients, Defendants’ present a potentially greater public health hazard than the cartels, whose products are distributed and sold through openly criminal means.

Exacerbating the problem even further, Defendants' illegal efforts and activities damage, if not destroy, the reputation and business of legitimate and essential providers, such as Plaintiff. Plaintiff brings these claims to redress the wrongs and damages inflicted by the Defendants.

IV. **FACTUAL BACKGROUND**

43. Plaintiff BioTE, formerly known as SottoPelle Texas, LLC, was established on or about July 10, 2009 and is headquartered in Irving, Texas.

44. Hormonal imbalance and replacement has become a public health issue in the United States and has attracted a great number of people and businesses seeking to provide relief for the countless people suffering from it. While most are legitimate and comply with the laws and regulations enacted to ensure patient safety, others unfortunately seek to take advantage of patient needs through shortcuts, illegal practices and open disregard for public safety.

45. In compliance with all applicable laws and regulations to ensure legitimate business practices and public safety, BioTE provides hormone replacement therapy to men and women who experience hormonal imbalances in their body. The primary method BioTE uses to accomplish its hormone replacement therapy is called Pellet Therapy. Pellet Therapy is conducted by inserting hormone pellets into the subcutaneous fat layer of the patient through an incision. BioTE's Pellet Therapy uses BioTE's custom and proprietary hormone pellet formula utilizing bio-identical and natural ingredients which act to keep hormone levels for men and women consistent throughout the day (hereinafter referred to as the "**BioTE Formula**"). Due to their administration via incision, the hormone pellets help to avoid the rollercoaster-like effects often found in orally administered or topically administered hormone therapy. The pellets BioTE uses contain bio-identical

hormones which are identical to the ones found in the human body. The pellets are very small, custom compounded therapies for symptoms that derive from hormonal imbalances.

46. The BioTE Formula is a unique, proprietary formula developed by BioTE through the expenditure of substantial time, money, resources and effort and provides BioTE with a unique advantage in the highly competitive marketplace.

47. BioTE through its legitimate business and medical practices has licensed its Pellet Therapy formula to over 3,000 physicians and physician groups across the United States.

48. In contrast to BioTE's legitimate and safe practices, Defendants Dan DeNeui and Terri DeNeui, husband and wife, and Michael Cole sought the alternative route of illegitimacy and public endangerment to "take advantage" of the Hormone replacement business. They are the architects of the Evexias/EvexiPEL – Farmakeio scheme, which through a maze of companies, flaunts the law and operates more closely to a drug cartel than a legitimate business enterprise. Evexias Health Solutions/EvexiPEL is the marketing company utilized by the Defendants. The Farmakeio entities provide the compounded drugs that Evexias Health Solutions/EvexiPEL sell. The Farmakeio entities do not employ any sales force. Rather, Evexias Health Solutions/EvexiPEL contracts with the sales force through purported independent contractor agreements.

49. Dan DeNeui and Terri DeNeui, on their own and sometimes in conjunction with others, own and operate the Evexias entities. Thomas is the medical director for Evexias Health Solutions/EvexiPEL. Dan DeNeui, Michael Cole, Graves, Harris, and Groves own and operate the Farmakeio entities. Graves is the Pharmacist-in-Charge of Farmakeio.

50. The sales force operating on behalf of the Evexias Health Solutions/EvexiPEL – Farmakeio scheme, who are referred to as "Practice Development Specialists" or "Development

Specialists” within the enterprise, are comprised of the following individuals and entities: Jacobsen, Guinn, Mueller, FAI, Dan Mikals, Lisa Mikals, Burns, Hill, Sandoval, Turcotte, Verrilli, Meegan, among other unknown individuals and entities (collectively referred to as the “**Development Specialists**”). Jeff DeNeui is the officer who directs the Development Specialists. Jones is the marketing director.

51. Evexias Medical Centers and Evexias HRT are medical clinics owned and operated by Terri DeNeui. Upon information and belief, Evexias Metrita Columbia, Evexias Anthem Columbia, and Evexias Anthem Alaska are also medical clinics recently opened up and operated by Terri DeNeui. Sheffield is the medical director for Evexias Medical Centers and Evexias HRT.

52. Defendants formulate, manufacture, market, sell and distribute unapproved new drugs that they claim are “lawfully compounded” drugs. Specifically, Defendants formulate, market, sell and distribute pellets to accomplish hormone replacement for persons men and women experiencing hormonal imbalances in their bodies (hereinafter referred to as the “Evexias Hormone Pellets”).

53. Defendants’ business model is as follows: (1) Farmakeio manufactures the Evexias Hormone Pellets for sale to physicians; (2) the Evexias Defendants, through the Development Specialists, market and sell the pellets to physicians around the United States for sale to their patients; and (3) Farmakeio pays Evexias Health Solutions a fee for each sale of Evexias Hormone Pellets that the Evexias Defendants’ Development Specialists generate.

54. Defendants do not obtain pre-market approval of the Evexias Hormone Pellets; which is specifically designed to ensure both the safety and effectiveness of drugs distributed to the public. Instead, Defendants purport to avoid the need for pre-market approval for the pellets by falsely representing that they are, and falsely promoting themselves as, certified under Section

503B of the Federal Food, Drug, and Cosmetic Act (“FDCA”).

55. Section 503B of the FDCA, codified at 21 U.S.C. section 353b, provides for an exemption from the drug-approval requirements flaunted by the Defendants, but is strictly limited to “outsourcing facilities” that are registered with FDA and that strictly comply with all of that provision’s conditions. Section 503B allows for the preparation of unapproved new drugs under certain strictly limited circumstances driven by specific public health needs that cannot be met by commercially available, approved drugs. A non-registered facility may not utilize the exceptions allowed under Section 503B - it is illegal to do so.

56. Defendants, and none of them, have ever registered with the FDA as a purported outsourcing facility under Section 503B. In fact, Defendants have never even submitted, or attempted to submit, an application under Section 503B. Defendants, nonetheless, hold themselves out to be approved under Section 503B.

57. Section 503B specifies that for a drug to be eligible for the exemption from the drug-approval requirement, the drug must be produced in a 503B facility and is compounded in accordance with the requirements of the section.

58. The Evexias Hormone Pellets are an unapproved drug that has not undergone the drug-approval process and Defendants are not a Section 503B facility. Defendants have included a steroid within the pellets that has not been tested for its efficacy, effectiveness or safety. In fact, adding triamcinolone, a corticosteroid that is known to cause fat necrosis, to the Evexias Hormone Pellets as Defendants do, and then injecting that pellet into the subdermal fat layer of the human body is most certainly not a safe and effective practice. But, Defendants, nonetheless, advertise and market the Evexias Hormone Pellets as superior, safe, effective and fully compliant.

59. Defendants have circumvented the drug-approval requirements in both federal and

state laws and have put patients at risk by exposing them to drugs that may or may not be safe and/or effective. Defendants have further placed the physicians that have received and are implanting the pellets into their patients at risk of causing harm to their patients and of distributing illegal, unapproved drugs.

60. The illegal manufacture and distribution of the Evexias Hormone Pellets from a Non-Section 503B facility is only part of the problem. Defendants, to enhance their illegal drug distribution network, have violated both state and federal law by illegally marketing and distributing the Evexias Hormone Pellets through persons “employed” by the Evexias Defendants as independent contractors (a violation of Texas Occ. Code 102.001 and 22 T.A.C. 2295.4 and potentially 42 USC 1320a-7b) and paying those independent contractors an illegal kickback based upon their respective sales of the Evexias Hormone Pellets to the physician offices (a violation of Texas Occ. Code 102.001 and 22 T.A.C. 2295.4 and potentially 42 USC 1320a-7b).

61. Defendants have made, and continue to make, false and misleading statements regarding themselves and their products in marketing, advertising and promotional materials, lectures, clinics and classes.

62. By way of example, in or around September 2018, Farmakeio distributed promotional and marketing materials to physicians and medical practices for its pellets. In the materials, as in the example below, Defendants represented that Farmakeio’s 503B registration was “pending.”



FARMAKEIO
SUPERIOR Custom Compounding



WHY CHOOSE FARMAKEIO?

- ✓ Accreditation Commission for Health Care (ACHC)
- ✓ Pharmacy Compounding Accreditation Board (PCAB)
- ✓ Sterile and Non-Sterile Compounds
- ✓ In compliance with chapters <795> and <797> of the U.S. Pharmacopoeia for compounding non-sterile and sterile preparations.
- ✓ Thousands of Formulations
- ✓ Extremely Competitive Pricing
- ✓ 503b (Registration Pending)
- ✓ SUPERIOR Products Produce SUPERIOR Patient Outcomes!



THESE HIGHLIGHTS ARE EXTREMELY IMPORTANT HOWEVER, WHAT REALLY SETS US APART IS OUR PEOPLE AND OUR CULTURE!

1. We are visionary. What we provide makes a significant difference for many individuals and affects relationships, families, organizations, communities and society.
2. We are infused and empowered with the spirit of accountability and excellence, both for our individual responsibilities and objectives, as well as our company's mission and goals.
3. We insist on treating our team and our customers with CARE, RESPECT GROWTH and PARTNERSHIP.
4. We have a faith-centered focus which is an integral aspect of our work.
5. We support and encourage participation and leadership while fulfilling our mission, with a sense of fun, respect and professionalism, and always maintain our
Commitment to Excellence to you our valued healthcare provider!

**To explore more, or to enroll as a practitioner, please contact
your Business Development Specialist:**

or visit us online at Farmakeio.com

63. In truth, neither Farmakeio nor any of the other Defendants had ever even applied, nor to this day have they applied, to become registered under Section 503B. So too, there is no recognized status under Section 503B for “registration pending.” Instead, it is completely

fabricated by the Defendants to mislead the physicians and the patients into believing that the Evexias Hormone Pellets are legal, safe, and fully compliant with federal and state law.

64. Defendants have further attempted to cause confusion among the general public, physicians and patients in need of hormone therapy that Defendants are the same company as Plaintiff, but with a different name, notwithstanding the fact that Evexias Health Solutions was first formed on January 9, 2018 and EvexiPEL even more recently than that. In Defendants' print advertising and the brochures distributed by the Development Specialists since March, 2018, Defendants have made the following representations:

- "Our founders developed the nation's largest providers of bio-identical hormone pellet therapy."
- "In collaboration with world-renowned experts, along with extended clinical observations, the EvexiPEL® Method has been created."
- Pellets – EvexiPEL ® HPT offers testosterone pellets that are specifically formulated and granulated by FarmaKEIO ® Compounding Pharmacy in Richardson, Texas, that contain trace amounts of a placatory substance, triamcinolone. The use of these pellets in thousands of patients have yielded better results in absorption, decreased scar tissue and far fewer extrusions."

65. Defendants have, in this regard, misrepresented their experience and time that they have been in business to reflect Plaintiff's long, legitimate and certified business experiences, instead of accurately disclosing Defendants' short, illegitimate and unlawful business existence and experience.

66. Defendants have further misrepresented the extent of its experience and expertise. In this regard, in addition to misrepresenting that Defendants are simply an extension of Plaintiff

and its facilities and certifications, in or about June, 2018 Defendants began misrepresenting to the physicians and the general public that Defendants have employed Dr. Neal Rouzier as the Chairman of Defendants' Medical Advisory Board. Although Dr. Rouzier was indeed employed as part of Plaintiff's faculty and a member of its Medical Advisory Board in the past, he has expressly rejected that role with Defendants.

67. Defendants have not just misrepresented the extent of their experience and expertise, however. Rather, Defendants have intentionally circumvented strict laws that are designed to ensure the safety and welfare of the public, and the integrity of the medical profession, to unfairly compete with Plaintiff and to misrepresent the integrity and propriety of their operations. Defendant Terri DeNeui has exceeded her license by delegating certain acts that she is required to perform under her license to other employees.

68. Specifically, while out-of-state trainees are being trained, and performing procedures on patients at Evexias, they are performing such procedures without first obtaining a Physician in Training limited license and are being supervised solely, in violation of Texas law. As a result, Defendants are facilitating and permitting out-of-state physicians to perform procedures in Texas without a licensed and qualified physician in the room.

FIRST CAUSE OF ACTION

Violation of Lanham Act

69. Plaintiff brings this action to stop Defendants from unlawfully manufacturing and selling unapproved new drugs under the false guise that they are engaged in lawful "compounding" and from engaging in false and misleading advertising and promotion of their unapproved new drugs. Federal and state law require drug manufacturers to demonstrate that their drugs are safe and effective in order to obtain regulatory approval to market them. Defendants purport to avoid

drug-approval requirements by falsely presenting their products as lawfully “compounded” when in fact Defendants’ products cannot lawfully be sold.

70. Section 43(a) of the Lanham Act protects those engaged in commerce from precisely this type of unfair competition and false advertising by creating a cause of action for those like Plaintiff who are harmed by it. 15 U.S.C. § 1125(a)(1).

71. Defendants have disregarded these basic provisions of federal and state law. Rather than invest the time and resources necessary to research, develop, and test their products in order to ensure that they are safe and effective and to obtain the regulatory approval and certification to market, sell and distribute them, Defendants are simply creating, marketing, and selling unapproved new drugs throughout the United States under the false guise of “compounding.” Defendants also mislead doctors about their business practices and products.

72. “Compounding” is “a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.” *Compounding and the FDA: Questions and Answers* (Oct. 6, 2015); *see also* United States Pharmacopeia—National Formulary (USP-NF), *General Chapter 1075, Good Compounding Practices*. Defendants’ manufacturing and marketing of standardized drugs without even seeking registration as a 503B registration is the antithesis of compounding.

73. The Entity Defendants are under common ownership and control and work closely together. Farmakeio creates new drugs by modifying FDA-approved drugs in ways that, at a minimum, create uncertainties about the safety and effectiveness of the resulting new drug. Defendants then distribute these unproven, unapproved, and potentially ineffective or dangerous drugs to physicians across the nation. Using an extensive sales force and marketing program, that

employs kickbacks and bribes to expand its reach and scope, Defendants falsely and misleadingly promote the unapproved Evexias Hormone Pellets as superior, compliant, lawful, and more effective than other legally available and distributed competitive products; including hormone products manufactured, marketed and distributed by Plaintiff.

74. Defendants' business model is unlawful, and Defendants are engaged in an unfair trade practice and false or misleading advertising, in that Defendants are expressly or implicitly misleading physicians into believing that Defendants' hormone replacement products are approved and safe; when, in fact, they are unapproved, their safety and effectiveness are unproven, and their sale is unlawful.

75. Ignoring state and federal drug-approval requirements provides Defendants an unfair competitive advantage over law-abiding compounding pharmacies like those relied upon by Plaintiff. Worse, it puts patients at risk by exposing them to medications and combinations of medications that have not been shown to be safe or effective.

76. Defendants falsely claim that they are entitled to sell their unproven and unapproved Evexias Hormone Pellets as lawfully compounded drugs when, in reality, they are engaged in nothing more than unlawful drug manufacturing and distribution.

77. When companies like Defendants misuse the narrow legal exemption available to legitimate Section 503B compounding pharmacies to mass manufacture and market unapproved medications and/or combinations of medications that are not tailored to an individual patient's medical needs under the guise of compounding, thousands of patients may be at risk. Mass manufacturing and marketing drugs under the guise of compounding also undermines the drug-approval requirements that are central to the protection of the public from drugs that are unsafe, ineffective, or both.

78. Unlike the compounding pharmacy that Plaintiff associates with, a registered 503B pharmacy, and other law-abiding compounding pharmacies, Defendants falsely and dangerously represent that they are a registered 503B pharmacy lawfully engaged in compounding; and are thus exempt from state and federal approval requirements. In doing so, Defendants tout the “lawfulness” of their activities. Defendants deceive physicians into buying the Evexias Hormone Pellets and other formulations from them—rather than buying approved 503B compounding pharmacies like the ones Plaintiff uses—by falsely and misleadingly assuring physicians that Defendants are a 503B certified compounding pharmacy, have the lawful right to sell and distribute their formulation to physician’s offices for subsequent sale to patients, and that the formulation of the Evexias Hormone Pellets are superior, safe, effective and approved. By ignoring drug-approval requirements and by misleading doctors about the legality of their business practices, Defendants are profiting at the expense of the public health and are unfairly competing with legitimate Section 503B compounding pharmacies such as those associated with Plaintiff.

79. Defendants brazenly flout the law on a massive scale. By mass manufacturing and distributing its drugs without the need to demonstrate that its drugs are safe and effective, Defendants have an enormous competitive advantage over legitimate compounding pharmacies that comply with the law.

80. Federal and state law require strict adherence to applicable drug and pharmacy laws for good reason. Drug laws and regulations are essential to ensuring the quality, safety, and effectiveness of drugs. When companies circumvent the drug-approval laws and regulations, safety and efficacy are unknown and patients are put at risk. The danger is not merely theoretical, but real and established.

81. Plaintiff brings this action under Section 43(a) of the Lanham Act to stop Defendants

from misleading doctors about their business and from unlawfully manufacturing, marketing, selling, and distributing the Evexias Hormone Pellets. Plaintiff seeks a declaration that Defendants' business practices in manufacturing and selling the Evexias Hormone Pellets, and in misleading doctors and patients about the lawfulness of their business model, violate the Lanham Act in multiple ways. First, Defendants violate the Lanham Act by misleading doctors into believing that their business model is legal. Second, Defendants violate the Lanham Act by violating federal and state law forbidding the manufacture, distribution, and sale of unapproved new drugs.

82. Defendants practices, as described in this Complaint, constitute unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C. §1125(a).

83. Defendants have violated the Lanham Act by using "false or misleading descriptions of fact" and "false or misleading representations of fact" in their commercial advertising or promotion that misrepresent "the nature, characteristics, [or] qualities" of their business practices and their products, as set forth above.

84. Plaintiff has suffered injury in fact and actual damages resulting from Defendants' false and misleading advertising and promotion and unfair competitive practices, including the loss of sales of Plaintiff's legitimate competitive product.

85. Plaintiff seeks actual damages that it has incurred as a result of Defendants' unlawful and deceptive business tactics, plus attorney's fees and court costs. *See* 15 U.S.C. § 1117(a); Fla. Stat. Ann. § 501.211(2).

86. Plaintiff further seeks disgorgement of Defendants' profits, for which Plaintiff now sues Defendants.

87. Plaintiff also seeks an injunction prohibiting Defendants from further

manufacturing, marketing, and selling the Evexias Hormone Pellets and from misleading doctors and patients. *See* 15 U.S.C. § 1116(a).

SECOND CAUSE OF ACTION

Racketeer Influenced and Corrupt Organizations Act (18 U.S.C. 1961, *et seq.*)

88. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

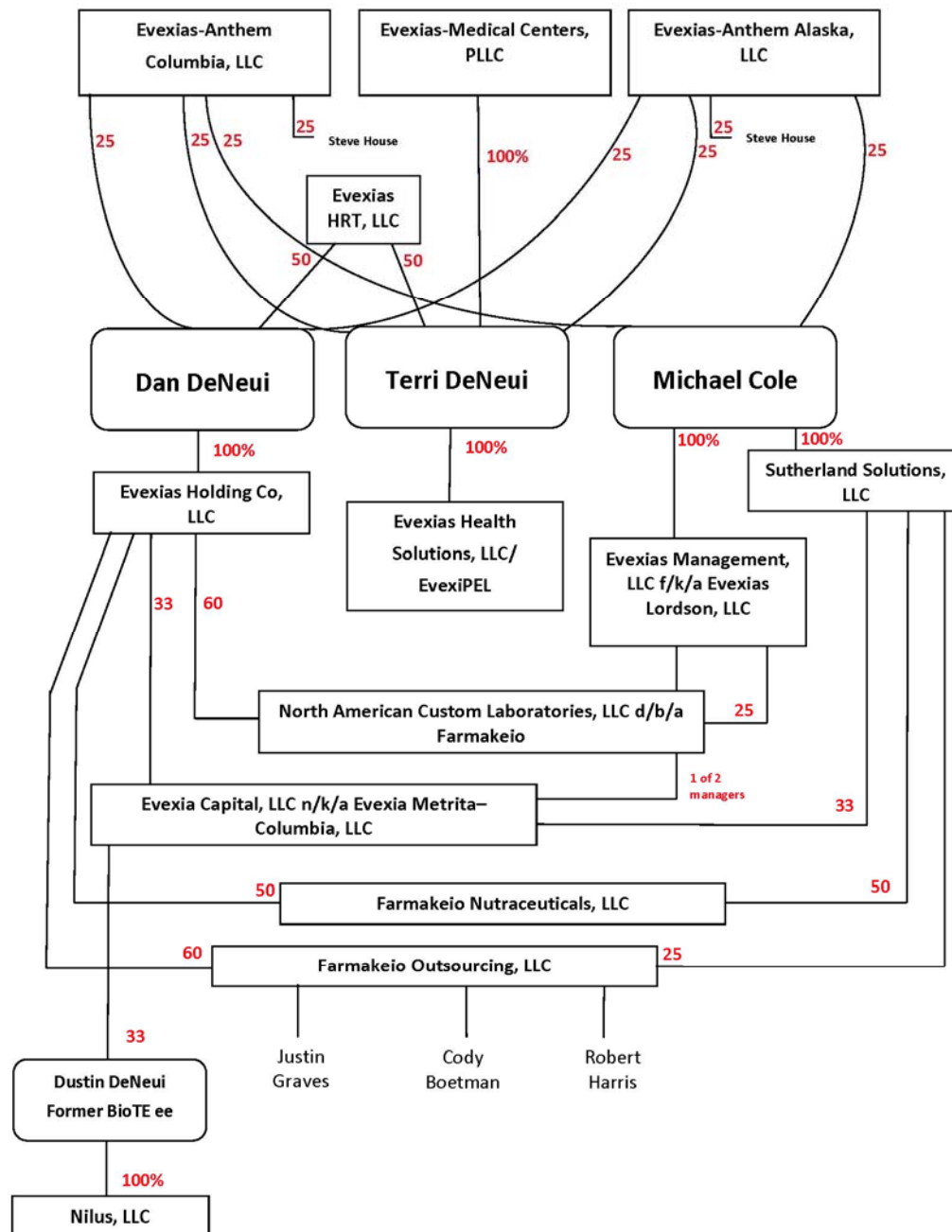
89. The Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise as defined in 18 U.S.C. § 1961(4) (the “RICO Enterprise”).

90. Since at least March, 2018, the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the Testosterone Therapy Market by unlawfully and surreptitiously paying illegal kickbacks and bribes, misrepresenting their certifications and qualifications, illegally supplying testosterone therapy pellets to medical providers for distribution to patients on warehousing basis, and illegally distributing unapproved formulations of their testosterone therapy pellets to patients.

91. Without a 503B Certification, the Defendants operated and continue to operate illegally by selling and distributing the unlawfully manufactured, marketed, and distributed Evexias Hormone Pellets to medical practitioners. Federal and State laws restrict the Defendants’ ability to manufacture, sell and distribute non-approved substances like the Evexias Hormone Pellets.

92. Without the means or desire to comply with the law, Defendants sought to initiate and expand the unlawful manufacture, sale, marketing and distribution of the Evexias Hormone Pellets through a complicated and all-encompassing RICO Enterprise comprised of layer upon

layer of shell-entities and holding companies, illegally employed “independent contractors,” and misrepresented personnel. As currently understood, the RICO Enterprise is comprised as follows:



93. In furtherance of the RICO conspiracy, Defendants acted in all major respects like

a drug cartel; engaging in the illegal manufacture of drugs, illegally selling their drugs, illegally distributing the drugs through the use of illegal independent contractors as “mules”, compensating the illegal independent contractors through illegal bribes and kickbacks, and, upon information and belief, funding the illegal Enterprise in part by failing to withhold and remit required payroll taxes to the applicable state and federal governments for illegal independent contractors.

94. Defendants, aiding and abetting one another and others known and unknown to Plaintiff, used and caused to be used facilities in interstate commerce with the intent to promote, manage, establish, carry on, distribute the proceeds of, and facilitate the promotion, management, establishment, carrying on, and distribution of the proceeds of an unlawful activity, that is, Commercial Bribery in violation of the Texas Commercial Bribery Statute, and thereafter, to perform and attempt to perform acts to promote, manage, establish, carry on, distribute the proceeds of, and facilitate the promotion, management, establishment, carrying on, and distribution of the proceeds of such unlawful activities. Defendants’ acts and omissions are violations of 18 U.S.C. 1952.

95. Plaintiff expressly pleads causes of action pursuant to the Racketeer Influenced Corrupt Organizations Act, as embodied in 18 U.S.C. §1962(a)-(d).

96. The facts establish that Defendants, individually and through the use of their maze of entities and with the help of their co-conspirators, have engaged in a pattern of racketeering activity that is in furtherance of and supported by the RICO Enterprise.

97. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail

fraud) and § 1343 (wire fraud).

98. The Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the Defendants’ regular use of the facilities, services, distribution channels, and employees of the Defendants. The Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

99. The Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through uniform misrepresentations, concealments and material omissions regarding their status as a Section 503B approved pharmacy, the legitimacy of their products, the efficacy of their products, the alleged superiority of their products and the unlawful distribution of their products.

100. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

101. The Defendants’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or

receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to manufacture, market, sell and distribute the illegal Evexias Hormone Pellets by means of false pretenses, misrepresentations, promises, and omissions.

- b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to manufacture, market, sell and distribute the illegal Evexias Hormone Pellets by means of false pretenses, misrepresentations, promises, and omissions.

102. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Defendants and/or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

- a. Shipments of the Evexias Hormone Pellets and related documents by mail or by private carrier affecting interstate commerce;
- b. Documents and communications that supported and/or facilitated the Defendants' solicited the purchase of the Evexias Hormone Pellets;
- c. Documents and communications that facilitated the manufacture, purchase and sale of the Evexias Hormone Pellets;
- d. Documents intended to facilitate the manufacture, sale and distribution of the Evexias Hormone Pellets, including bills of lading, invoices, shipping records, reports and correspondence;
- e. Documents for processing and receiving payment for the Evexias Hormone Pellets;
- f. Payments from the physicians and physician officers;
- g. Kickbacks paid to the independent sales agents for the Evexias Hormone Pellets;
- h. Deposits of proceeds from Defendants' manufacture, sale and distribution of the Evexias Hormone Pellets; and
- i. Other documents and things, including electronic communications.

103. Defendants pattern of criminal conduct also include the following:

- a. The payment of illegal bribes/kickbacks;
- b. The illegal manufacture of controlled substances;
- c. The illegal sale of controlled substances;
- d. The illegal distribution of controlled substances; and
- e. The violation of state penal and common law statutes by and through the illegal kickbacks, and manufacture, sale and distribution of controlled

substances.

104. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff, the physicians to whom the Evexias Hormone Pellets were marketed and sold and the patients to whom they were administered.

105. Defendants calculated and intentionally crafted the enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on its victims, including Plaintiff.

106. In designing and implementing the scheme, Defendants knew the physicians and patients rely on the integrity of the pharmaceutical companies to provide objective and reliable information regarding Defendants' products and their manufacture, sale and distribution.

107. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

108. The Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury and the relationship between the Defendants' conduct and Plaintiff's injury are logical and not speculative. It was foreseeable to the Defendants that when they engaged in the RICO activities alleged herein, it would provide the means by which the Defendants could illegally and wrongfully compete with Plaintiff and unlawfully divert Plaintiff's business to the enterprise and that Plaintiff would be logically, substantially, and foreseeably harmed as a result.

109. The Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury and the relationship between the Defendants'

conduct and Plaintiff's injury is logical and not speculative.

110. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

111. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

112. The Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of their pattern and practice of illegal activities – leading to the distribution of hundreds of thousands of doses, and perhaps millions of doses, of the unapproved drug – Evexias Hormone Pellets – into the market.

113. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing, selling, marketing and distributing the Evexias Hormone Pellets.

114. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of the illegal Evexias Hormone Pellets. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated event.

WHEREFORE, PREMISES CONSIDERED, BioTE prays that Defendants be cited to appear and answer, and that:

- (1) The Court issue injunctive relief;
- (2) BioTE be awarded judgment against Defendants for actual damages of a minimum of \$10,000,000.00, consequential, incidental and special damages;
- (3) BioTE be awarded judgment against Defendants for punitive damages in not less than three times the amount of BioTE's actual damages;
- (4) BioTE be awarded judgment against Defendants for BioTE's attorneys' fees, costs of court, along with pre- and post-judgment interest as allowed by law; and,
- (5) BioTE be awarded such other and additional relief, at law or in equity, to which it may show itself justly entitled.

Respectfully submitted,

By: /s/ Ryan K. Lurich

LAWRENCE J. FRIEDMAN

Texas Bar No. 07469300

Email: lfriedman@fflawoffice.com

RYAN K. LURICH

Texas Bar No. 24013070

Email: rlurich@fflawoffice.com

ERIC M. FRIEDMAN

Texas Bar No. 24090106

Email: efriedman@fflawoffice.com

FRIEDMAN & FEIGER, LLP

5301 Spring Valley Road, Suite 200

Dallas, Texas 75254

Telephone (972) 788-1400

Facsimile (972) 788-2667

ATTORNEYS FOR PLAINTIFF

BIOTE MEDICAL, LLC

#857374